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(54) **CATHETER DELIVERY DEVICE**

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See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

3,642,068 A 2/1972 Fitch et al.  
4,719,853 A 1/1988 Bowers  
(Continued)

FOREIGN PATENT DOCUMENTS

CA 2202870 A1 5/1996  
DE 3019995 A1 12/1981  
(Continued)

OTHER PUBLICATIONS

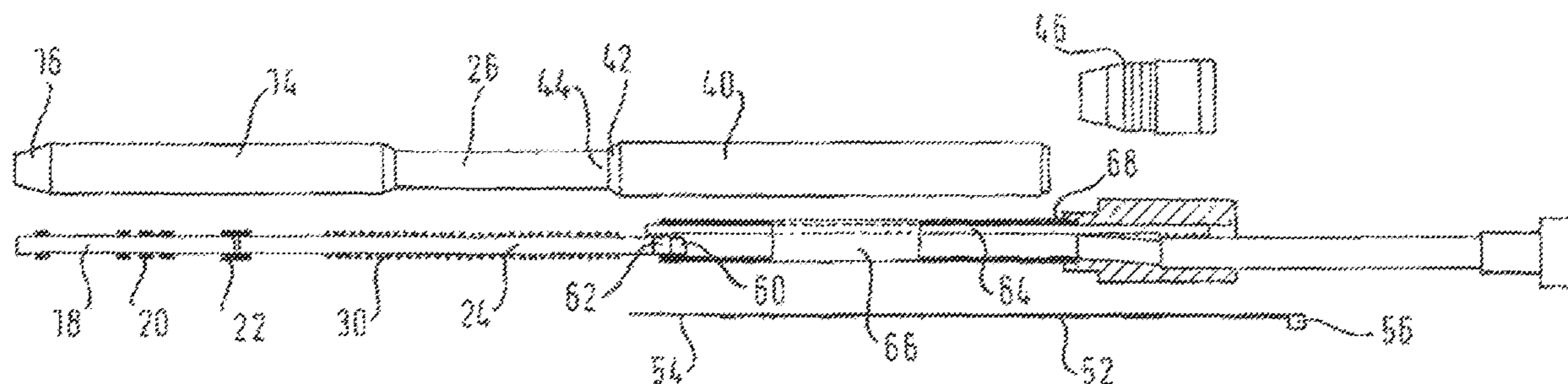
CA 3,050,184 filed Jun. 10, 2009, Notice of Application found Allowable dated May 20, 2021.  
(Continued)

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(57) **ABSTRACT**

A catheter delivery device for a self-expanding stent is described. The delivery device includes a distal catheter component and a distal sheath that releases the stent by moving proximally relative to the distal catheter component and the stent. A proximal catheter shaft including a tube and a pull wire within a lumen of the tube may be provided, the pull wire being attached to the distal sheath such that pulling the pull wire proximally relative to the tube pulls the distal sheath proximally to release the stent progressively. A casing tube may be provided to surround the catheter shaft, the casing tube having a distal end that receives telescopically a proximal end of the distal sheath. A method of making a delivery device for implantation of a self-expanding stent is also described.

**13 Claims, 2 Drawing Sheets**



**Related U.S. Application Data**

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(56) **References Cited**

U.S. PATENT DOCUMENTS

5,120,323 A 6/1992 Shockey et al.  
 5,159,937 A 11/1992 Tremulis  
 5,246,008 A 9/1993 Mueller  
 5,456,665 A 10/1995 Postell et al.  
 5,474,563 A 12/1995 Myler et al.  
 5,484,425 A 1/1996 Fischell et al.  
 5,484,444 A 1/1996 Braunschweiler et al.  
 5,507,766 A 4/1996 Kugo et al.  
 5,533,987 A 7/1996 Pray et al.  
 5,573,520 A 11/1996 Schwartz et al.  
 5,591,194 A 1/1997 Berthiaume  
 5,628,754 A 5/1997 Shevlin et al.  
 5,649,908 A 7/1997 Itoh  
 5,676,659 A 10/1997 McGurk  
 5,702,373 A 12/1997 Samson  
 5,702,418 A 12/1997 Ravenscroft  
 5,718,159 A 2/1998 Thompson  
 5,741,429 A 4/1998 Donadio, III et al.  
 5,772,669 A 6/1998 Vrba  
 5,951,539 A 9/1999 Nita et al.  
 5,957,930 A 9/1999 Vrba  
 5,968,052 A 10/1999 Sullivan, III et al.  
 6,013,019 A 1/2000 Fischell et al.  
 6,027,863 A 2/2000 Donadio, III  
 6,042,588 A 3/2000 Munsinger et al.  
 6,053,903 A 4/2000 Samson  
 6,107,004 A 8/2000 Donadio, III  
 6,254,611 B1 7/2001 Vrba  
 6,258,080 B1 7/2001 Samson  
 6,296,622 B1 10/2001 Kurz et al.  
 6,306,145 B1 10/2001 Leschinsky  
 6,331,186 B1 12/2001 Wang et al.  
 6,342,066 B1 1/2002 Toro et al.  
 6,350,278 B1 2/2002 Lenker et al.  
 6,352,553 B1 3/2002 van der Burg et al.  
 6,352,561 B1 3/2002 Leopold et al.  
 6,355,060 B1 3/2002 Lenker et al.  
 6,361,555 B1 3/2002 Wilson  
 6,368,344 B1 4/2002 Fitz  
 6,371,979 B1 4/2002 Beyar et al.  
 6,375,676 B1 4/2002 Cox  
 6,380,457 B1 4/2002 Yurek et al.  
 6,387,118 B1 5/2002 Hanson  
 6,391,050 B1 5/2002 Broome  
 6,391,051 B2 5/2002 Sullivan, III et al.  
 6,402,760 B1 6/2002 Fedida  
 6,413,269 B1 7/2002 Bui et al.  
 6,425,898 B1 7/2002 Wilson et al.  
 6,432,129 B2 8/2002 DiCaprio  
 6,443,979 B1 9/2002 Stalker et al.  
 6,468,298 B1 10/2002 Pelton  
 6,482,211 B1 11/2002 Choi  
 6,482,221 B1 11/2002 Hebert et al.  
 6,488,694 B1 12/2002 Lau et al.  
 6,505,066 B2 1/2003 Berg et al.  
 6,514,280 B1 2/2003 Gilson  
 6,517,547 B1 2/2003 Feeser et al.  
 6,517,569 B2 2/2003 Mikus et al.  
 6,520,983 B1 2/2003 Colgan et al.  
 6,530,947 B1 3/2003 Euteneuer et al.  
 6,554,841 B1 4/2003 Yang  
 6,572,643 B1 6/2003 Gharibadeh  
 6,576,806 B1 6/2003 Slaugh et al.  
 6,579,297 B2 6/2003 Bicek et al.  
 6,582,460 B1 6/2003 Cryer  
 6,592,569 B2 7/2003 Bigus et al.  
 6,592,617 B2 7/2003 Thompson

6,599,296 B1 7/2003 Gillick et al.  
 6,599,304 B1 7/2003 Selmon et al.  
 6,605,109 B2 8/2003 Fiedler  
 6,607,551 B1 8/2003 Sullivan et al.  
 6,616,996 B1 9/2003 Keith et al.  
 6,626,934 B2 9/2003 Blaeser et al.  
 6,629,981 B2 10/2003 Bui et al.  
 6,629,992 B2 10/2003 Bigus et al.  
 6,641,606 B2 11/2003 Ouriel et al.  
 6,656,212 B2 12/2003 Ravenscroft et al.  
 6,656,213 B2 12/2003 Solem  
 6,660,031 B2 12/2003 Tran et al.  
 6,663,666 B1 12/2003 Quiachon et al.  
 6,676,666 B2 1/2004 Vrba et al.  
 6,676,693 B1 1/2004 Belding et al.  
 6,689,120 B1 2/2004 Gerdts  
 6,695,862 B2 2/2004 Cox et al.  
 6,699,274 B2 3/2004 Stinson  
 6,702,843 B1 3/2004 Brown et al.  
 6,726,712 B1 4/2004 Raeder-Devens et al.  
 6,726,714 B2 4/2004 DiCaprio et al.  
 6,736,839 B2 5/2004 Cummings  
 6,743,219 B1 6/2004 Dwyer et al.  
 6,749,627 B2 6/2004 Thompson et al.  
 6,773,446 B1 8/2004 Dwyer et al.  
 6,780,199 B2 8/2004 Solar et al.  
 6,786,918 B1 9/2004 Krivoruchko et al.  
 6,790,221 B2 9/2004 Monroe et al.  
 6,827,731 B2 12/2004 Armstrong et al.  
 6,830,575 B2 12/2004 Stenzel et al.  
 6,843,802 B1 1/2005 Villalobos et al.  
 6,849,084 B2 2/2005 Rabkin et al.  
 6,858,034 B1 2/2005 Hijlkema et al.  
 6,860,898 B2 3/2005 Stack et al.  
 6,866,669 B2 3/2005 Buzzard et al.  
 6,884,259 B2 4/2005 Tran et al.  
 6,899,727 B2 5/2005 Armstrong et al.  
 6,926,732 B2 8/2005 Derus et al.  
 6,939,352 B2 9/2005 Buzzard et al.  
 6,942,688 B2 9/2005 Bartholf et al.  
 6,945,989 B1 9/2005 Betelia et al.  
 7,001,423 B2 2/2006 Euteneuer et al.  
 7,025,773 B2 4/2006 Gittings et al.  
 7,052,511 B2 5/2006 Weldon et al.  
 7,052,513 B2 5/2006 Thompson  
 7,074,236 B2 7/2006 Rabkin et al.  
 7,118,005 B2 10/2006 Shimazaki  
 7,147,657 B2 12/2006 Chiang et al.  
 7,163,552 B2 1/2007 Diaz  
 7,172,617 B2 2/2007 Colgan et al.  
 7,172,618 B2 2/2007 Lupton  
 7,198,636 B2 4/2007 Cully et al.  
 7,297,302 B2 11/2007 Berg et al.  
 7,303,580 B2 12/2007 Parker  
 7,320,702 B2 1/2008 Hammersmark et al.  
 7,387,640 B2 6/2008 Cummings  
 7,454,422 B2 11/2008 Chan et al.  
 7,455,688 B2 11/2008 Furst et al.  
 7,462,192 B2 12/2008 Norton et al.  
 7,468,070 B2 12/2008 Henry et al.  
 7,517,361 B1 4/2009 Ravenscroft  
 7,550,001 B2 6/2009 Dorn et al.  
 7,553,322 B2 6/2009 Dorn et al.  
 7,717,949 B2 5/2010 Dorn  
 7,758,624 B2 7/2010 Dorn et al.  
 7,867,267 B2 1/2011 Sullivan et al.  
 8,075,606 B2 12/2011 Dorn  
 8,206,348 B2 6/2012 McDermott et al.  
 8,652,193 B2 2/2014 Dorn  
 9,750,625 B2 9/2017 Dorn  
 2001/0034549 A1 10/2001 Bartholf et al.  
 2001/0049547 A1 12/2001 Moore  
 2001/0056299 A1 12/2001 Thompson  
 2002/0016597 A1 2/2002 Dwyer et al.  
 2002/0028984 A1 3/2002 Hayakawa et al.  
 2002/0077691 A1 6/2002 Nachtigall  
 2002/0128678 A1 9/2002 Petersen  
 2002/0133127 A1 9/2002 Collins  
 2002/0133141 A1 9/2002 Sparks et al.

(56)

## References Cited

## U.S. PATENT DOCUMENTS

2003/0050686 A1 3/2003 Raeder-Devens et al.  
 2003/0055447 A1 3/2003 Lee et al.  
 2003/0093106 A1 5/2003 Brady et al.  
 2003/0114911 A1 6/2003 Lupton  
 2004/0006380 A1 1/2004 Buck et al.  
 2004/0073293 A1 4/2004 Thompson  
 2004/0087933 A1 5/2004 Lee et al.  
 2004/0106977 A1 6/2004 Sullivan et al.  
 2004/0127912 A1 7/2004 Rabkin et al.  
 2004/0148009 A1 7/2004 Buzzard et al.  
 2004/0153049 A1 8/2004 Hewitt et al.  
 2004/0153137 A1 8/2004 Gaschino et al.  
 2004/0193180 A1 9/2004 Buzzard et al.  
 2004/0215229 A1 10/2004 Coyle  
 2004/0215317 A1 10/2004 Cummings  
 2004/0230286 A1 11/2004 Moore et al.  
 2004/0267281 A1 12/2004 Harari et al.  
 2005/0004515 A1 1/2005 Hart et al.  
 2005/0004553 A1 1/2005 Douk  
 2005/0021123 A1 1/2005 Dorn et al.  
 2005/0027345 A1 2/2005 Horan et al.  
 2005/0033403 A1 2/2005 Ward et al.  
 2005/0065590 A1 3/2005 Shelso  
 2005/0065591 A1 3/2005 Moberg et al.  
 2005/0080476 A1 4/2005 Gunderson et al.  
 2005/0090887 A1 4/2005 Pryor  
 2005/0090890 A1 4/2005 Wu et al.  
 2005/0165352 A1 7/2005 Henry et al.  
 2005/0182475 A1 8/2005 Jen et al.  
 2005/0209671 A1 9/2005 Ton et al.  
 2005/0209675 A1 9/2005 Ton et al.  
 2005/0246008 A1 11/2005 Hogendijk et al.  
 2005/0246010 A1 11/2005 Alexander et al.  
 2005/0288762 A1 12/2005 Henderson et al.  
 2006/0004438 A1 1/2006 Alexander et al.  
 2006/0015168 A1 1/2006 Gunderson  
 2006/0020321 A1 1/2006 Parker  
 2006/0030923 A1 2/2006 Gunderson  
 2006/0041302 A1 2/2006 Malewicz  
 2006/0058865 A1 3/2006 Case et al.  
 2006/0074409 A1 4/2006 Schuermann  
 2006/0074478 A1 4/2006 Feller  
 2006/0089627 A1 4/2006 Burnett et al.  
 2006/0095110 A1 5/2006 Moberg et al.  
 2006/0100687 A1 5/2006 Fahey et al.  
 2006/0100688 A1 5/2006 Jordan et al.  
 2006/0106455 A1 5/2006 Furst et al.  
 2006/0111769 A1 5/2006 Murray  
 2006/0116752 A1 6/2006 Norton et al.  
 2006/0184225 A1 8/2006 Pryor  
 2006/0184227 A1 8/2006 Rust  
 2006/0190069 A1 8/2006 Baker-Janis et al.  
 2006/0200221 A1 9/2006 Malewicz  
 2006/0206189 A1 9/2006 Furst et al.  
 2006/0224112 A1 10/2006 Lentz  
 2006/0229697 A1 10/2006 Gerdts et al.  
 2006/0235502 A1 10/2006 Belluche et al.  
 2006/0247661 A1 11/2006 Richards et al.  
 2006/0253184 A1 11/2006 Amplatz  
 2006/0259118 A1 11/2006 Pal et al.  
 2006/0259123 A1 11/2006 Dorn  
 2006/0259124 A1 11/2006 Matsuoka et al.  
 2006/0271150 A1 11/2006 Andreas et al.  
 2006/0271151 A1 11/2006 McGarry et al.  
 2006/0282147 A1 12/2006 Andreas  
 2006/0282148 A1 12/2006 Hammersmark et al.  
 2006/0282149 A1 12/2006 Kao  
 2006/0282152 A1 12/2006 Beyerlein et al.  
 2006/0282157 A1 12/2006 Hill et al.  
 2007/0027521 A1 2/2007 Andreas et al.  
 2007/0027522 A1 2/2007 Chang et al.  
 2007/0043420 A1 2/2007 Lostetter  
 2007/0043421 A1 2/2007 Mangiardi et al.  
 2007/0043726 A1 2/2007 Chan et al.  
 2007/0043728 A1 2/2007 Chan et al.

2007/0055339 A1 3/2007 George et al.  
 2007/0055340 A1 3/2007 Pryor  
 2007/0060910 A1 3/2007 Grandt et al.  
 2007/0073373 A1 3/2007 Bonsignore  
 2007/0073379 A1 3/2007 Chang  
 2007/0073391 A1 3/2007 Bourang et al.  
 2007/0100412 A1 5/2007 Dwyer et al.  
 2007/0100413 A1 5/2007 Dwyer et al.  
 2007/0100421 A1 5/2007 Griffin  
 2007/0100422 A1 5/2007 Shumer et al.  
 2007/0106364 A1 5/2007 Buzzard et al.  
 2007/0118201 A1 5/2007 Pappas et al.  
 2007/0118207 A1 5/2007 Amplatz et al.  
 2007/0123971 A1 5/2007 Kennedy et al.  
 2007/0142892 A1 6/2007 Dave et al.  
 2007/0168014 A1 7/2007 Jimenez et al.  
 2007/0179519 A1 8/2007 Huisun  
 2007/0191864 A1 8/2007 Shumer  
 2007/0191865 A1 8/2007 Pappas  
 2007/0198048 A1 8/2007 Behan et al.  
 2007/0198050 A1 8/2007 Ravenscroft et al.  
 2007/0198076 A1 8/2007 Hebert et al.  
 2007/0199360 A1 8/2007 Sarac et al.  
 2007/0203563 A1 8/2007 Hebert et al.  
 2007/0208407 A1 9/2007 Gerdts et al.  
 2007/0213813 A1 9/2007 Von Segesser et al.  
 2007/0219612 A1 9/2007 Andreas et al.  
 2007/0219613 A1 9/2007 Kao et al.  
 2007/0219617 A1 9/2007 Saint  
 2007/0233224 A1 10/2007 Leynov et al.  
 2007/0244540 A1 10/2007 Pryor  
 2007/0250149 A1 10/2007 Von Oepen et al.  
 2007/0250151 A1 10/2007 Pereira  
 2007/0255390 A1 11/2007 Duche et al.  
 2007/0260301 A1 11/2007 Chuter et al.  
 2007/0265694 A1 11/2007 Sarac et al.  
 2007/0270779 A1 11/2007 Jacobs et al.  
 2007/0270932 A1 11/2007 Headley et al.  
 2007/0270937 A1 11/2007 Leanna  
 2007/0293930 A1 12/2007 Wang et al.  
 2008/0009934 A1 1/2008 Schneider et al.  
 2008/0033570 A1 2/2008 Blitz et al.  
 2008/0058722 A1 3/2008 Von Oepen et al.  
 2008/0065014 A1 3/2008 Von Oepen et al.  
 2008/0071345 A1 3/2008 Hammersmark et al.  
 2008/0077223 A1 3/2008 Fischell et al.  
 2008/0103581 A1 5/2008 Goto  
 2008/0114435 A1 5/2008 Bowe  
 2008/0114442 A1 5/2008 Mitchell et al.  
 2008/0183272 A1 7/2008 Wood et al.  
 2008/0208310 A1 8/2008 McDermott et al.  
 2008/0234796 A1 9/2008 Dorn  
 2008/0255651 A1 10/2008 Dwork  
 2008/0262590 A1 10/2008 Murray  
 2008/0275541 A1 11/2008 Furst et al.  
 2008/0288043 A1 11/2008 Kaufmann et al.  
 2008/0319524 A1 12/2008 Yachia et al.  
 2009/0036967 A1 2/2009 Cummings  
 2009/0054972 A1 2/2009 Norton et al.  
 2009/0105802 A1 4/2009 Henry et al.  
 2009/0156998 A1 6/2009 Arana et al.

## FOREIGN PATENT DOCUMENTS

DE 3910157 A1 10/1989  
 EP 0303487 A2 2/1989  
 EP 0437795 A1 7/1991  
 EP 0473045 A1 3/1992  
 EP 0517075 A1 12/1992  
 EP 0608853 A2 8/1994  
 EP 0680351 A1 11/1995  
 EP 0688576 A1 12/1995  
 EP 0792656 A1 9/1997  
 EP 0807444 A2 11/1997  
 EP 0810003 A2 12/1997  
 EP 0823262 A2 2/1998  
 EP 0904795 A1 3/1999  
 EP 1364611 A1 11/2003  
 EP 1457215 A1 9/2004

(56)

References Cited

OTHER PUBLICATIONS

FOREIGN PATENT DOCUMENTS

EP	1656963	A1	5/2006
EP	1709987	A1	10/2006
EP	1747793	A1	1/2007
EP	1834610	A1	9/2007
EP	1852138	A1	11/2007
JP	2006-271565	A	10/2006
JP	2007-175440	A	7/2007
JP	2008-104657	A	5/2008
WO	1993015785	A1	8/1993
WO	1996013228	A1	5/1996
WO	1996036298	A1	11/1996
WO	1997043949	A1	11/1997
WO	1998012988	A1	4/1998
WO	1999015219	A1	4/1999
WO	1999044541	A1	9/1999
WO	1999064098	A1	12/1999
WO	2000012031	A1	3/2000
WO	2001078627	A1	10/2001
WO	2001087180	A2	11/2001
WO	2005053574	A2	6/2005
WO	2005072391	A2	8/2005
WO	2006034008	A2	3/2006
WO	2006127931	A2	11/2006
WO	2006133958	A1	12/2006
WO	2006133959	A1	12/2006
WO	2006133960	A1	12/2006
WO	2007004221	A1	1/2007
WO	2007065420	A1	6/2007
WO	2007076114	A2	7/2007
WO	2007138608	A1	12/2007
WO	2008005666	A1	1/2008
WO	2008036156	A1	3/2008
WO	2008093851	A1	8/2008

JP 2011-512895 Office Action dated Mar. 27, 2013.  
 JP 2011-512895 Office Action dated Mar. 28, 2014.  
 JP 2011-512895 Office Action dated Oct. 10, 2014.  
 PCT/EP2009/004199 filed Jun. 10, 2009 International Preliminary Report on Patentability dated Nov. 5, 2010.  
 PCT/EP2009/004199 filed Jun. 10, 2009 Search Report dated Oct. 19, 2009.  
 PCT/EP2009/004199 filed Jun. 10, 2009 Written Opinion dated Oct. 19, 2009.  
 U.S. Appl. No. 12/481,985, filed Jun. 10, 2009 Advisory Action dated May 21, 2014.  
 U.S. Appl. No. 12/481,985, filed Jun. 10, 2009 Advisory Action dated Oct. 22, 2012.  
 U.S. Appl. No. 12/481,985, filed Jun. 10, 2009 Final Office Action dated Feb. 27, 2014.  
 U.S. Appl. No. 12/481,985, filed Jun. 10, 2009 Final Office Action dated Jun. 29, 2012.  
 U.S. Appl. No. 12/481,985, filed Jun. 10, 2009 Final Office Action dated Mar. 12, 2015.  
 U.S. Appl. No. 12/481,985, filed Jun. 10, 2009 Non-Final Office Action dated Aug. 15, 2013.  
 U.S. Appl. No. 12/481,985, filed Jun. 10, 2009 Non-Final Office Action dated Dec. 22, 2011.  
 U.S. Appl. No. 12/481,985, filed Jun. 10, 2009 Non-Final Office Action dated Oct. 2, 2014.  
 U.S. Appl. No. 15/659,496, filed Jul. 25, 2017 Advisory Action dated Jun. 4, 2020.  
 U.S. Appl. No. 15/659,496, filed Jul. 25, 2017 Final Office Action dated Apr. 1, 2020.  
 U.S. Appl. No. 15/659,496, filed Jul. 25, 2017 Non-Final Office Action dated Jan. 19, 2021.  
 U.S. Appl. No. 15/659,496, filed Jul. 25, 2017 Non-Final Office Action dated Sep. 27, 2019.  
 U.S. Appl. No. 15/659,496, filed Jul. 25, 2017 Notice of Allowance dated Apr. 29, 2021.

Fig. 1

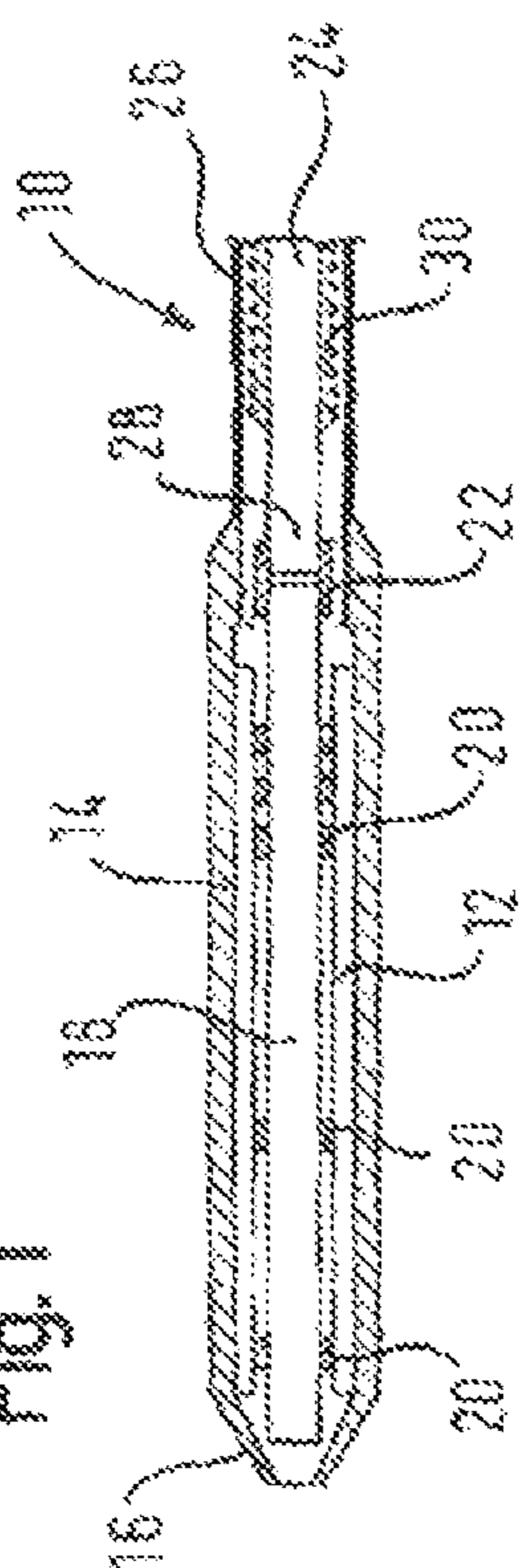


Fig. 2

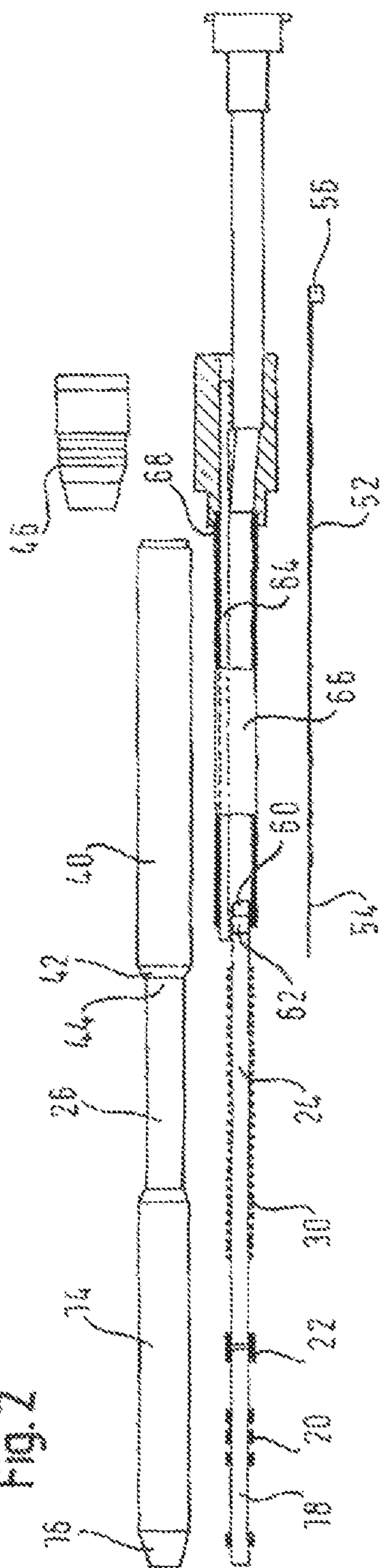
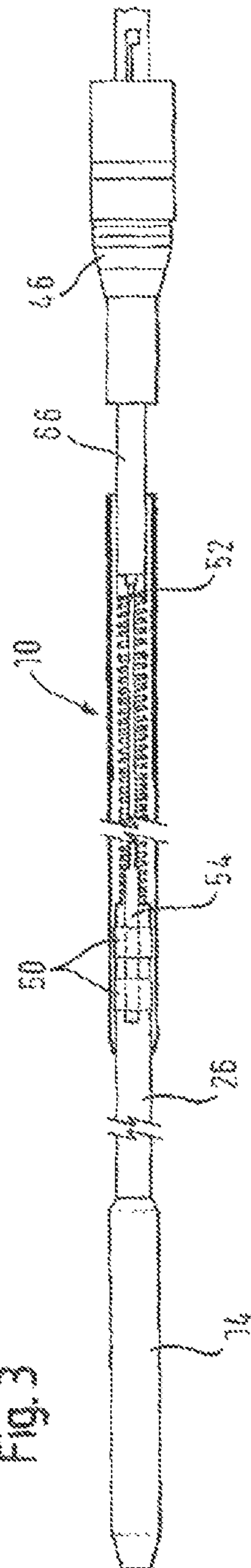
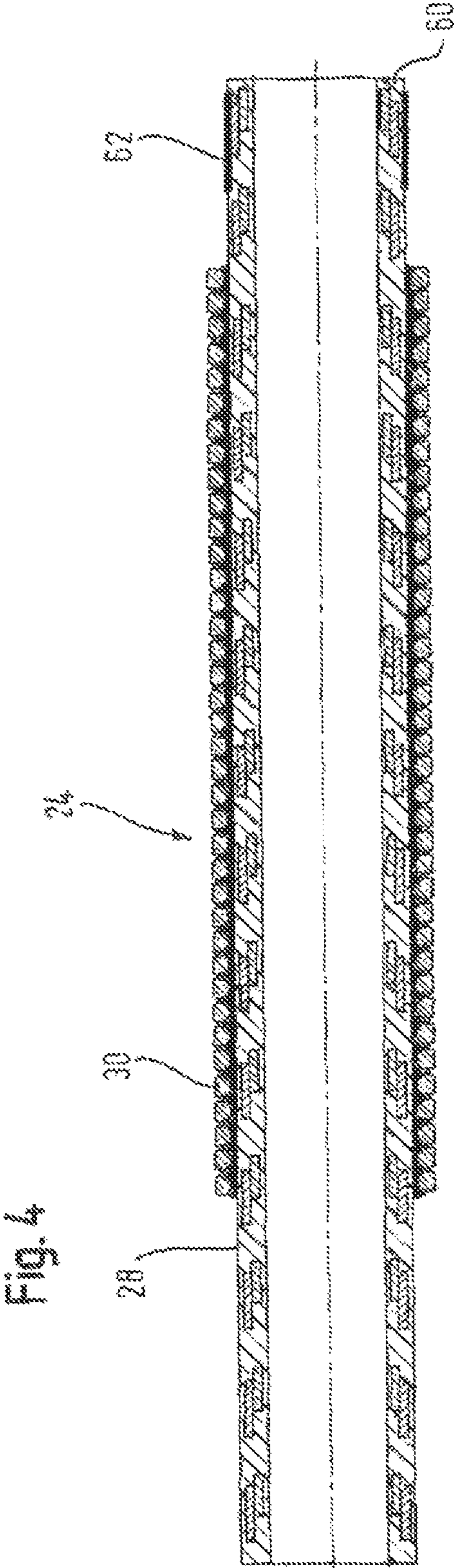


Fig. 3





**CATHETER DELIVERY DEVICE**

## PRIORITY

This application is a continuation of U.S. patent application Ser. No. 15/659,496, filed Jul. 25, 2017, now U.S. Pat. No. 11,109,990, which is a continuation of U.S. patent application Ser. No. 12/481,985, filed Jun. 10, 2009, now U.S. Pat. No. 9,750,625, which claims priority to U.S. Provisional Application No. 61/060,568, filed Jun. 11, 2008, and to United Kingdom Patent Application No. 0810749.2, filed Jun. 11, 2008, each of which is incorporated by reference in its entirety into this application.

## TECHNICAL FIELD

This invention relates to a catheter which is a delivery device for a self-expanding stent to be delivered to a stenting location in the body trans-luminally. The device is of the “pull wire” type and is designed for delivery of covered stents of significant length, that represent a tougher delivery task than a short bare stent. The device described below is of the “over the wire” category. However, the present invention can also be applied to “rapid exchange” catheter delivery devices. Guidewire diameters of 18 or 35 “thou” are conventional and contemplated for use with this invention. Covered stents with deployed diameters in a range of from 6 mm to 18 mm are contemplated.

## BACKGROUND

The present applicant has progressively developed delivery devices for covered stents. One example is to be found in WO 2005/053574, which is incorporated by reference in its entirety into this application. The present invention carries such architecture forward into the technical field of covered stents that are lengthier (maybe up to 120 mm, or even beyond) and so put greater demands on the strength of the delivery system during deployment of the stent, when a sheath surrounding the stent has to be pulled proximally, relative to the stent, to release the stent into the bodily lumen to be stented, progressively, starting at the distal end of covered stent. Readers will appreciate that it is characteristic of such catheter delivery devices that one of two end-to-end components is in endwise tension (the components responsible for pulling the sheath proximally) while the other of the two end-to-end components (the one that prevents the stent from being drawn proximally with the proximally moving sheath) is in end-to-end compression during progressive deployment of the stent. In general, designers of catheter delivery devices for self-expanding stents try to keep the passing diameter of the catheter to a minimum, which self-evidently conflicts with the design imperative that the end-to-end component in compression does not buckle or concertina, or otherwise lose its length integrity, during stent deployment. The present invention sacrifices ultimate narrowness of passing diameter to the objective of enhanced performance in delivering relatively lengthy covered stents, for which endwise stresses in the catheter delivery device, during deployment of the stent, are likely to be higher than for shorter stents that are bare rather than covered.

Catheter delivery devices that exhibit a “pull wire” are attractive for tasks where the end-to-end stresses are relatively large, because a wire is well able to sustain endwise tension, but not so well adapted to sustain an endwise compressive stress. Better for that task is a tube. Thus, in a coaxial system, one with the tube carrying the compressive

stress, and the wire within it carrying the tensile stress, will likely perform better than a system arranged the other way around. However, at the distal end of the system, where the stent is located, it is the outside sheath that is in tension, and the inside catheter element, that stops the stent moving proximally, that is in compression. Thus, somewhere between the proximal and distal end of the catheter delivery system of a pull wire architecture, there needs to be an inversion, to transfer the tensile stress from the radially inner pull wire to the radially outer sheath surrounding the stent. Clearly, any length interval between the transfer zone and the distal end of the stent, in which a relatively small diameter component of the catheter system is required to carry the endwise compressive stress during stent deployment, needs to be strong enough to retain its lengthwise integrity during such stent deployment. Self-evidently, the length of that portion should be reduced, to the extent possible.

A further problem with transfer zones in pull wire systems is to minimize any propensity for the catheter system to buckle at any particular point along its length. Evidently, there is a challenge to incorporate a transfer zone somewhere along the length of the catheter shaft, while at the same time avoiding any points long the length of the catheter where there is an increased risk of buckling.

## SUMMARY

Catheter delivery devices in accordance with the present invention can feature novelty in the architecture of the part of the system that withdraws proximally to release the stent. Alternatively, they can exhibit novelty in that part of the system that retains the stent against proximal withdrawal during stent deployment. Preferably the novelty is in both of these component parts of the system, working synergistically together. Each of the contributions to the architecture of the catheter delivery device constitutes an invention in its own right, but the combination of the improved architecture pull back component, with the improved architecture of the component that carries the end-to-end compression during stent deployment, can yield synergistic results that allow the deployment through narrow tortuous lumens, of remarkably lengthy covered stent prostheses.

According to a first aspect of the present invention there is provided a catheter delivery device in which a casing tube surrounds the catheter shaft and has a distal end that receives telescopically a proximal end of the distal sheath of the device, with a pull wire fixed to a proximal end zone of the distal sheath within the lumen of the casing tube.

Normally, the casing tube proximal end is fixed to a hub of an actuating device (otherwise called “hand unit”). Conveniently, the delivery device includes a retaining ring that retains the pull wire on the radially outside surface of a proximal end zone of the distal sheath, the ring embracing the radially outside surface of the distal sheath, near its proximal end. Usefully, the distal end zone of the pull wire is thinned and given the shape of part of a cylindrical surface with a radius that corresponds to that of the radially outer cylindrical surface of the distal sheath near its proximal end, whereby the thinned end zone of the pull wire can lie flush, or close to flush, with a radially outside surface of the distal sheath and, conveniently, clamped to that outside surface by the retaining ring, which is conveniently a swaged ring.

Readers skilled in the art will be able to envisage other ways of extending a sheath into a pull wire. For example, the material of the sheath could itself be continued proximally, to form the pull wire.

In one preferred embodiment, the distal sheath exhibits a diving tube proximal of the location of the stent. The inventor calls this component of the device a “diving” tube because it “dives” into the open distal end of the casing tube and slides proximally within the lumen of the casing tube, during deployment of the stent. The diving tube has an outside diameter slightly smaller than that of more distal portions of the distal portion of the distal sheath, that embrace the stent. Conveniently, the distal end of the diving tube is fixedly received inside the open proximal end of a distal portion of the distal sheath. At the distal end of the distal portion of the distal sheath an inwardly tapered atraumatic tip can be provided, for the catheter device as a whole. Normally, the pull wire will be attached to a zone of the diving tube relatively close to the proximal end of the diving tube, inside the lumen of the casing tube.

Conventionally, in stent delivery systems, an atraumatic tip is provided on an axial component that extends through the lumen of the stent, with the stent sheath terminating proximally of that atraumatic tip. Such arrangements are compatible with the present invention and can provide embodiments of it.

In another aspect of the present invention, the inner catheter component of the delivery device includes a proximal sheath that has a lumen that contains the catheter shaft of the delivery device. It has an open distal end that receives a proximal end of the distal catheter component, side-by-side with the distal end of the catheter shaft. The proximal sheath and the distal catheter component together provide a guidewire lumen that runs the full length of the delivery device, thereby to render the delivery system a member of the “over the wire” type. In one preferred embodiment, the distal end of the catheter tube carries, to one side of the tube axis, a transfer ring that embraces the proximal end of the distal catheter component. We call this ring a “transfer” ring because it marks the transfer of endwise compressive stress during deployment of the stent, between the outer coaxial component constituted by the catheter shaft tube, and the inner coaxial component at the distal end of the delivery device, inside the distal sheath that is pulled proximally to release the stent.

Readers will be able to envisage alternatives to a transfer ring. Depending on the materials of construction of the catheter tube and the distal catheter component, these two components could be joined, side by side, with techniques such as gluing, fusion welding, strapping together or brazing, as well as form-fitting and other ways of achieving a mechanical interference that resists axial shortening.

As mentioned above, the catheter system as a whole must resist any tendency to kink under endwise compression. Transition zones are particularly vulnerable to unwanted kinking. It may therefore be worthwhile to install at the side by side component transfer zone an extra splint or sleeve, to enhance resistance to kinking in this zone.

The conventional way to stop a stent from moving proximally during proximal withdrawal of the surrounding sheath in deployment of the stent, is to provide a form of “stop ring” that the proximal end of the stent butts up against, whenever the stent seeks to move proximally. Normally, such an arrangement imposes no undue compressive stresses on any part of the stent matrix. However, in a case where the stent might be vulnerable to excessive end-to-end compressive stress, a better arrangement is to give the stent cylinder a measure of support, against proximal movement, over a greater part of the length of the stent than just the proximal end surface of the stent cylinder. Since the catheter delivery device of the present invention is specifically adapted for use

with lengthy covered stents, it is advantageous to continue the distal catheter component into a stent support tube that is located, in use, inside the lumen of the stent, and supports the stent around that lumen, against proximal withdrawal relative to the distal catheter component, during proximal withdrawal of the surrounding sheath. In one preferred embodiment, the stent support tube is provided with a plurality of annular cushions that mechanically interfere with the covered luminal surface of the stent radially outside the stent support tube.

The word “cushion” is to be interpreted liberally. For example, a simple spiral protruding radially, to press against the luminal surface of the prosthesis or implant, covered stent or bare stent, can serve the desired purpose. Other arrangements are already within the published patent literature, and becoming more numerous as stent lengths continue to increase. For example, the present applicant has described various arrangements in U.S. Pat. Nos. 8,287,582 and 7,717,949, each of which is incorporated by reference in its entirety into this application.

Applicant has previously developed delivery systems for self-expanding stents in which the distal sheath and stent are free to rotate coaxially, relative to the catheter shaft. While this is still possible to engineer, with the present invention, it is envisaged also to have the stent support tube fixed to the catheter shaft without freedom to rotate thereby fixing (via the stent) the outer sheath against rotation relative to the catheter shaft. With such rotation inhibited, there is no risk that the pull wire can wrap itself around the other catheter shaft component.

The distal catheter component, where it lies proximal of the proximal end of the stent, needs to have enough column strength to resist the compressive stress imposed on it when the stent is being released. A known way to improve the column strength of a catheter component is to wrap it with a helical wire. Accordingly, in one preferred embodiment of the present invention a compound catheter portion of the distal catheter component includes a helix of wire to stiffen the compound catheter portion when the compound catheter portion is in end-to-end compression.

Readers will be well aware of the importance of achieving a high enough resistance to compressive stress, and adequate column strength. Also in this area of design, the patent literature offers the reader a range of alternatives to a helical wire wrapping. Specifically, a tube of metal, for example stainless steel or PHYNOX with a multitude of through wall slits transverse to its length direction, can combine high flexibility with high column strength. For a relevant disclosure, see WO 2006/133960 and EP-A-1656963, each of which is incorporated by reference in its entirety into this application.

In one embodiment (not shown) the proximal end zone of the distal catheter component comprises a length portion that exhibits a multitude of slits with their length direction transverse to the length of the distal catheter component. Such slits can increase the flexibility in bending of the distal catheter component, at least in its proximal end zone. Usefully, the slitted length portion is extended distally towards the location of the proximal end of the stent. The distal extension would normally be all the way to the proximal end of the stent but might be less than all the way, for example, if the distal catheter component exhibits a change of material, from metal to polymer, in a zone located proximally of the proximal end of the stent.

Conveniently, the delivery device includes a connection tube with a lumen that receives, in its distal end, the proximal end of the stent support tube and, in its proximal



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open end, the distal end of the compound catheter portion. Adhesive compositions can be used to build the combination of the distal catheter component. The annular cushions on the stent support tube can have other forms, indeed, any suitable form of “embossing” that is capable of resisting relative axial movement of the stent, proximally, relative to the distal catheter component.

It is suggested above that cushions within the lumen of the stent can take over completely from a “pusher” ring that abuts the proximal end of the stent. Nevertheless, a ring to abut the proximal end of the stent can also be provided here. In one embodiment, it assists the cushions. In another embodiment it is deliberately spaced away from the proximal end of the prosthesis, and abuts that proximal end only in the event that the cushions somehow fail to prevent all proximal movement of the prosthesis during its deployment.

#### BRIEF DESCRIPTION OF THE DRAWINGS

For a better understanding of the present invention, and to show more clearly how the same may be carried into effect, reference will now be made, by way of example, to the accompanying drawings, in which:

FIG. 1 is a lengthwise diametral section of a distal end portion of a first embodiment of catheter delivery device in accordance with the present invention;

FIG. 2 is a schematic lengthwise diametral section of the delivery device of FIG. 1, partly exploded to show individual components separately;

FIG. 3 is a longitudinal diametral section, as in FIGS. 1 and 2, but showing the device in its assembled form; and

FIG. 4 is a longitudinal diametral section through the compound catheter portion.

#### DETAILED DESCRIPTION

The illustrated delivery system 10 is for delivering a covered stent 12 that can be seen in FIG. 1 compressed inside a distal sheath 14 that has an atraumatic tapered distal tip 16. The stent being a self-expanding stent, it is pressing on the radially inner cylindrical surface of the outer sheath 14. Inside the radially compressed stent 12 is a stent support tube 18 that defines a guidewire lumen (not visible in FIG. 1) and carries on its outer cylindrical surface a plurality of annular cushions 20. For covered stents with a length of more than 100 mm we propose three such cushions near the proximal end of the stent, one at the distal end of the stent, and one part-way along the length of the stent. For shorter stents, the cushion part-way along the stent is likely not needed. The cushions are made of DYMAX material and each can be of a length along the axis of the stent that is in the area of 2 mm to 4 mm. Depending how the cushions are attached to the support tube 18, it may be beneficial to provide at the distal end of the tube a safety element, namely some form of a stopper that will stop any annular cushion inadvertently sliding off the distal end of the support tube during deployment of the stent.

In FIG. 1, the stent support tube 18 has a proximal end that is received within a short connection tube 22, that also receives the distal end of a compound catheter portion 24 based on a tube of polyimide with braid reinforcement within its annular wall thickness, that is destined to carry a lengthwise compression stress when the distal sheath 14 is pulled proximally away from the stent 12 to release it from the delivery system. What pulls the distal sheath 14 from around the sheath is a proximal portion of the distal sheath which we call a “diving sheath” 26 that has an outside

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diameter marginally smaller than the inside diameter of the distal sheath 14 and a distal end that is received inside the lumen at the proximal end of the distal sheath 14, where it is fixed by an adhesive composition. The diving sheath 26 surrounds the compound catheter component, with clearance. We propose that it be of braided polyamide with a wall thickness of 100  $\mu\text{m}$ . In the case of relatively large diameter prosthesis, deliverable with a relatively small diameter catheter shaft, it may be that the inside diameter of the distal sheath 14 is significantly bigger than the outside diameter of the distal end of the driving sheath. In such a case it may be useful to provide an intermediate spacer sleeve between the two components.

The compound catheter component in the lumen of the diving sheath has a polyimide shaft element 28 that defines a guidewire lumen and carries glued on its outer cylindrical surface a helical wind of fine wire 30 which serves to stiffen the tube 28 against bending, without too much loss of bending flexibility, especially when the tube 28 is under endwise compression.

Before leaving FIG. 1, we draw it to the attention of readers that the distal sheath 14, without the diving sheath 26, can serve as a pre-assembly during manufacture of the catheter delivery device, with the stent support tube 18 and stent 12 being inserted into the sheath 14 to constitute the sub-assembly. At a later stage in manufacture, the tube 28 of the compound catheter portion can be connected to the stent support tube 18, for example, by heat-shrinking the polyamide connection tube 22 around both the tube 28 and the stent support tube 18, using a PET shrink tube at around 200° C. After such shrinking, the PET tube is removed and discarded. Thereafter, the diving sheath 26 can be introduced into the distal sheath 14 with or without an intervening spacer sleeve, and fixed to it with adhesive.

Turning now to FIG. 2 of the drawings, we see components of the delivery device arranged in an “exploded” form, just enough to separate the components of the inner and outer coaxial members. Thus, the sub-assembly of distal sheath 14 and diving sheath 26 is shown displaced sideways from the stent support tube but coaxial with a casing tube 40 that has a distal end 42 that receives a proximal end 44 of the diving sheath 26. The proximal end of the casing tube 40 is fixed by adhesive to a strain-relieving hub 46 of a hand unit that will actuate the deployment of the stent from the delivery device. During deployment of the stent, the distal sheath 14 and diving sheath 26 move proximally, but the casing tube 40 does not, so that the proximal end of the diving sheath 26 slides proximally down the lumen of the casing tube 40, from the open distal end 42.

We briefly turn to FIG. 3 to complete the description of the proximal movement of the distal sheath. FIG. 3 shows a pair of retaining bands 50 that are swaged into rings around a proximal end zone of the diving sheath 26. These rings press onto the outer cylindrical surface of the diving sheath 26, the distal end of a pull wire 52 which has a flattened portion 54 at its distal end that lies underneath the swaged bands 50, pressed against the surface of the diving sheath 26. Laser welding is used, to weld the pull wire to the retaining bands 50. It is tension in the pull wire 52, imposed from proximal of the proximal end 56 of the pull wire 52, that pulls the diving sheath, and hence the distal sheath 14, away from the stent 12.

Reverting to FIG. 2 of the drawings, we see again the stent support tube 18, connection tube 22 and compound catheter portion 24. We also see the proximal end 60 of the tube 28 of the compound catheter portion 24 being held within a transfer ring 62 that is swaged around the proximal end 60.

That transfer ring is welded to a catheter shaft tube **64** of PHYNOX alloy that defines a lumen that channels the pull wire **52**.

A proximal sheath **66** surrounds the catheter tube **64**, nested, but with the catheter tube **64** away from the rotational axis of the proximal sheath **66**. That leaves most of the cross-section of the lumen of the proximal sheath **66** free for flushing liquids and a guidewire. The guidewire lumen defined by the proximal sheath **66** continues into the lumen of the compound catheter portion and stent support tube. The proximal end **68** of the sheath **66** is set in the same hub **46** as carries the proximal end of the casing tube **40**, so that there is no relative endwise movement between the casing tube **40** and the proximal sheath **66**. Please note that the ratios of diameter to length in FIGS. **2** and **3** of the drawings bears no relation to reality, in which the overall length of the device likely will be substantially more than a 100 cm whereas the passing diameter contemplated is less than 3 mm (7 French or 8 French). It appears from FIG. **2**, for example, that the diving sheath **26** will abut the proximal sheath **66**, at least when the stent is deployed. However, looking at FIG. **3**, we can see a very substantial end-to-end gap between the diving sheath **26** and the distal end of the proximal sheath **66**. The representation in FIG. **3** is misleading as to the length of the proximal sheath **66**. In practice, it occupies a very substantial portion of the total length of the system. The total length of the distal sheath **14**, diving sheath **26** and compound catheter portion **24**, proximally as far as the transfer ring **62**, will be much less than 50% of the total length of the catheter system. In reality, and prior to deployment of the implant, the proximal end of the diving sheath **26** is a considerable distance away, distally, from the distal end of the proximal sheath **66**, as shown in FIG. **3**, but contrary to the impression given by the exploded diagram of FIG. **2**.

For a more detailed description of the compound catheter portion, see the text below, that describes what is shown in FIG. **4** of the drawings.

In operation, the delivery device with its distal end zone looking like it is represented in FIG. **1** is introduced trans-luminally into the body, and advanced as is known per se, until the distal end is at the location in the body where stenting is desired. At that point, when the stent is to be deployed, the hand unit is actuated, to impose a tensile stress on the pull wire **52**, from its proximal end **56**. This tensile stress passes through to the distal sheath **14**, which moves proximally, with sliding of the diving sheath **26** into the casing tube **40**. The stent **12** would be inclined to be carried proximally with the outer sheath **14**, except that it is prevented from so doing, by the interaction with the inner surfaces of the covered stent by the cushions **20** of the stent support tube **18**. Any tendency of the stent support tube **18** to move proximally with the outer sheath **14** is resisted by compression stress that is generated all the way from the actuation unit along the catheter tube **64**, through the transfer ring **62** and along the compound catheter portion **24**, up to the end-to-end abutment with the stent support tube **18** inside the connection ring **22**, and thence to the cushions **20** and the stent.

After successful deployment of the stent, retraction and removal of the delivery device is relatively straightforward. The cylindrically outside surfaces of the catheter system are generally smooth, and likely anyway to be coated with a lubricious coating. The atraumatic distal tip **16** of the system has stretched to pass proximally over the covered stent but is still residually inwardly tapered during withdrawal of the system. Inside the stent, there is no bulky tip structure that

has to pass through the lumen of the stent, from beyond the distal end to proximally of the stent lumen. Instead, the only structure that has to slip proximally out of the stent lumen is that of the stent support tube **18**, which represents a minimal tendency to snag on the inside of the stent.

Turning now to FIG. **4** of the drawings, we find the compound catheter portion **24** shown at a larger scale so that its constructional details can be seen more clearly. The portion **24** is based on a polyimide tube **28** that includes within its annular wall thickness a braid of flat wire. The annular wall thickness is 0.075 mm and the outer diameter is 1.16 mm. The inner diameter is 1.01 mm and the flat braiding wire has a rectangular cross-section of thickness 0.013 mm and width of 0.076 mm. The braid is based on SS304W steel material, braided at 100 PPI (crossing points per inch). There are 16 wire bands altogether in the braid.

Turning now to the helical wind of multi-strand wire on the outer cylindrical surface of the polyimide tube **28**, this is glued to the tube with cyanoacrylate glue and, after wrapping, the outside diameter of the helical coil is 1.5 mm (to a tolerance of 0.02 mm). After mounting on the tube **28**, the helical coil is ground to a final outside diameter of 1.4 mm. As is evident from drawing FIG. **4**, the helical coil does not cover the entire axial length of the compound catheter component. Proximally, it stops short of the transfer ring **62**. Distally, it stops 50 mm short of the distal end of the tube **28**, well short of the connection tube **28** and, as can be seen in drawing FIG. **1**, well short of the proximal end of the sheath **14** which lies radially outside the covered stent **12**.

Variations in the construction of the delivery device shown in the drawings will be evident to those skilled in the art. Materials selection is part of the routine burden of the delivery system designer, as is choice of methods for reliably connecting individual components of the delivery system. A number of individual features of the stent delivery system are known in themselves, but there are multitudes of features routine to use in stent delivery devices that can be mixed and matched to achieve particular requirements of the delivery task to be performed. The number of design considerations to be taken into account is almost infinite. Thus, putting together a synergistic combination of individual components, that permits the delivery of longer covered stents than hitherto, with greater radial stenting force than hitherto, beyond the capability of any delivery system hitherto available, represents a valuable and important contribution to the art.

#### INDUSTRIAL APPLICABILITY

A catheter delivery device is disclosed, that has a specific architecture capable of delivering through tortuous bodily lumens with a narrow diameter a covered self-expanding stent with a greater length, and higher stenting force, than would hitherto have been possible.

What is claimed is:

1. A method of making a delivery device for implantation of a self-expanding stent, comprising:

preparing an inner delivery component, comprising:

coupling a proximal catheter component to a compound catheter component, wherein a pull wire tube is nested in the proximal catheter component, and wherein a pull wire is positioned in the pull wire tube; and

coupling the compound catheter component to a distal catheter component, the distal catheter component configured to carry the self-expanding stent, wherein the proximal catheter component, the compound

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- catheter component, and the distal catheter component together define a contiguous guidewire lumen from a proximal end of the inner delivery component to a distal end of the inner delivery component;
- preparing an outer delivery component, comprising:
- inserting a casing tube into a diving sheath such that relative motion between the casing tube and the diving sheath is permitted; and
  - securing the diving sheath to a distal sheath;
- disposing the outer delivery component over the inner delivery component, wherein the casing tube surrounds the proximal catheter component and the distal sheath surrounds the distal catheter component;
- connecting a distal end of the pull wire to the diving sheath; and
- attaching the proximal catheter component to a hub.
2. The method according to claim 1, further comprising fixing a proximal end of the casing tube to the hub.
3. The method according to claim 1, wherein connecting the distal end of the pull wire to the diving sheath comprises swaging a band around the pull wire and the diving sheath.
4. The method according to claim 1, wherein the distal end of the pull wire comprises a flattened portion, and wherein connecting the distal end of the pull wire to the diving sheath comprises pressing the flattened portion against an outer surface of the diving sheath.
5. The method according to claim 4, further comprising laser welding a pair of retaining bands around the flattened portion and the diving sheath.
6. The method according to claim 1, wherein the distal sheath comprises a distal end tapering radially inwardly to provide an atraumatic tip.

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7. The method according to claim 1, wherein the compound catheter component has a lumen diameter equivalent to a lumen diameter of the distal catheter component, and wherein coupling the compound catheter component to the distal catheter component comprises heat shrinking a polyamide connection tube around the compound catheter component and the distal catheter component.
8. The method according to claim 1, wherein the compound catheter component comprises a braid reinforcement in an annular wall.
9. The method according to claim 8, wherein the braid reinforcement includes a helix of flat wire braided at 100 crossing points per inch.
10. The method according to claim 9, wherein the braid reinforcement comprises 16 wire bands having a rectangular shape.
11. The method according to claim 1, wherein the distal catheter component includes embossing on an outer surface, the embossing engaging with a luminal surface of the self-expanding stent.
12. The method according to claim 1, wherein the distal catheter component comprises a length portion including a multitude of slits with a length direction of the multitude of slits transverse to the length portion of the distal catheter component, the length portion with the multitude of slits increasing the flexibility in bending of a proximal end zone of the distal catheter component.
13. The method according to claim 12, wherein the length portion with the multitude of slits extends to a proximal end of the self-expanding stent.

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